IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

LOCATELLI et al.

Atty. Ref.: 1303-122

Serial No. 09/831,820

Group: 1637

Filed: June 5, 2001

Examiner: FREDMAN, J.

For: METHOD FOR THE QUANTITATIVE DETECTION OF NUCLEIC ACIDS

* * * * * * * * * * *

October 9, 2002

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE

Responsive to the Official Action dated September 10, 2002, the applicants elect, with traverse Group I (claims 1-17) and species III (HHV-8) for purposes of the initial search. The Examiner is requested to reconsider and withdraw the restriction requirement as the claims belonging to Groups I and II share common special technical features represented by the calibrator and its specific probes. Such features distinguish the claimed subject matter from the cited art define an inventive contribution thereto.

Specifically, the document cited by the Examiner as "X" reference (Gibson et al., "D1"), discloses a quantitative RT-PCR assay suitable for RNA quantitation which is based on the use of an internal control which, with respect to the target, "should use the same primers, contain similar guanine + cytosine (G+C) content and be of equal or similar length" (page 995, first column). In contrast, the control used in the claimed

invention (referred to as "calibrator") must have the same sequence as the target molecule, "apart from the region complementary to the probe that has been modified so as to preserve the same (*not similar*) nucleotide composition but with a random sequence" (page 8, lines 15-16 of the application). This means that the natural order of the target nucleotides is changed in that region of the calibrator while their respective ratios are maintained unvaried, so that primers and probes can anneal with the randomized region at very similar Tm (see Example 1, page 11 – last paragraph). This aspect is crucial and determines an inventive contribution over D1. Among the advantages associated with the claimed invention, and which cannot be found in D1, there is for example the possibility to obtain an absolute quantitation of nucleic acids starting from a single, known amount of the calibrator in a single reaction tube, without generating a calibration curve through serial dilutions of the internal control. In addition, the efficiency of the method, measured as the number of samples assayed per unity of time, is significantly increased as well as its accuracy and precision. Further, according to the claimed method, the amplification of target and calibrator is carried out in the same reaction tube, independently of their relative amounts (in contrast to D1, see page 996 – first column).

In addition, the applicants note that the claimed kit is specifically designed for carrying out the method for quantitative detection of nucleic acids of the invention, not for different purposes.

The Examiner's unsupported and unexplained reliance on the technical merits of the citation of an "X" reference in an International Search Report as the sole basis for

requiring restriction is, with due respect, believed to be inappropriate. The Examiner is requested to provide a technical explanation of the cited art in view of the claims in the event the restriction requirement is maintained.

Reconsideration and withdrawal of the restriction requirement and issuance of an early and favorable Action on the merits of all the claimed subject matter are requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____

B. J. Sadoff
Reg. No. 36,663

BJS:plb

1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of Atty Dkt. 1303-122
C# M#
LOCATELLI et al. Group Art Unit: 1637
Serial No. 09/831,820 Examiner: FREDMAN, J.
Filed: June 5, 2001 Date: October 9, 2002
Title: METHOD FOR THE QUANTITATIVE DETECTION OF NUCLEIC ACIDS

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

RESPONSE/AMENDMENT/LETTER

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

Fees are attached as calculated below:

Total effective claims after amendment **0** minus highest number previously paid for **20** (at least 20) = 0 x $ 18.00	$	0.00
Independent claims after amendment **0** minus highest number previously paid for **3** (at least 3) = 0 x $ 84.00	$	0.00
If proper multiple dependent claims now added for first time, add $280.00 (ignore improper)	$	0.00
Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) ($110.00/1 month; $400.00/2 months; $920.00/3 months)	$	0.00
Terminal disclaimer enclosed, add $ 110.00	$	0.00
☐ First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) ($740.00) ☐ Please enter the previously unentered , filed ☐ Submission attached	$	0.00
Subtotal	$	**0.00**
If "small entity," then enter half (1/2) of subtotal and subtract ☐ Applicant claims "small entity" status. ☐ Statement filed herewith	-$	0.00
Rule 56 Information Disclosure Statement Filing Fee ($180.00)	$	0.00
Assignment Recording Fee ($40.00)	$	0.00
Other:		**0.00**
TOTAL FEE ENCLOSED	$	**0.00**

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

1100 North Glebe Road, 8th Floor
Arlington, Virginia 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100
BJS:b

NIXON & VANDERHYE P.C.
By Atty: B. J. Sadoff, Reg. No. 36,663

Signature: _____